EUROPEAN
COMMISSION

Brussels, 28.9.2018
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COMMISSION IMPLEMENTING DECISION

of 28.9.2018

on the transfer of the marketing authorisation granted by Decision C(2000)1407 for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH AND DUTCH TEXTS ARE AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular Article 6 thereof,

Having regard to the application submitted by Merck Sharp & Dohme Limited on 29 June 2018 under Article 3 of Regulation (EC) No 2141/96,

Having regard to the opinion of the European Medicines Agency, formulated on 17 July 2018 on the transfer of a marketing authorisation,

Whereas:

(1) The medicinal product "PegIntron - Peginterferon alfa-2b", entered in the Community register of medicinal products under the number EU/1/00/131 and authorised by Commission Decision C(2000)1407 of 25 May 2000, remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) A change of holder of the marketing authorisation for which the transfer application is made is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already authorised.

(3) It is appropriate to set the date by which all the operations resulting from the transfer of the marketing authorisation must be completed.

(4) The European Medicines Agency has given a favourable opinion.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 286, 8.11.1996, p. 6.
[3] OJ L 311, 28.11.2001, p. 67.

(5) Decision C(2000)1407 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(6) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2000)1407 should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2000)1407 of 25 May 2000 to Merck Sharp & Dohme Limited for the medicinal product "PegIntron - Peginterferon alfa-2b", entered in the Community register of medicinal products under No EU/1/00/131, is transferred to Merck Sharp & Dohme B.V..

Article 2

Decision C(2000)1407 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

1) The transfer referred to in Article 1 shall be authorised from the date of notification of this Decision.

2) All the operations resulting from this transfer must be completed by 29 March 2019 at the latest.

Article 4

This Decision is addressed to:
1. Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, Nederland
and
2. Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom.

Done at Brussels, 28.9.2018

For the Commission

Xavier PRATS MONNÉ
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION